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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/087,273 | 03/01/2002 | John R. Gordon | 4616-62430 | 3115 |

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| EXAMINER | |
|---|---|
| MERTZ, PREMA MARIA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/087,273 | GORDON ET AL. | |
| | Examiner | Art Unit | |
| | Prema M Mertz | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-79* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-22, 30-37, are drawn to a polynucleotide encoding a protein of amino acid sequence set forth in SEQ ID NO:1, a vector, a host cell and a process for producing the polypeptide, classified in Class 435, subclass 69.1.

Group 2. Claims 1-22, 30-37, are drawn to a polynucleotide encoding an antagonist protein as set forth in claim 1 (iii), a vector, a host cell and a process for producing the polypeptide, classified in Class 435, subclass 69.1.

Group 3. Claims 1-22, 30-37, are drawn to a polynucleotide encoding an antagonist protein as set forth in claim 1 (iv), a vector, a host cell and a process for producing the polypeptide, classified in Class 435, subclass 69.1.

Group 4. Claims 1-22, 30-37, are drawn to a polynucleotide encoding an antagonist protein as set forth in claim 1 (v), a vector, a host cell and a process for producing the polypeptide, classified in Class 435, subclass 69.1.

Group 5. Claims 23, 65, 78, drawn to an antagonist protein as set forth in claims 23 (i), and claim 65(i), classified in Class 530, subclass 324.

Group 6. Claims 23, 65, 78, drawn to an antagonist protein as set forth in claims 23 (ii), and claim 65(ii), classified in Class 530, subclass 324.

Group 7. Claims 23, 65, 78, drawn to an antagonist protein as set forth in claims 23 (iii), and claim 65(iii), classified in Class 530, subclass 324.

Group 8. Claims 24-29, drawn to a method of treating a condition by administering the antagonist protein as set forth in claim 23 (i), classified in Class 424, subclass 85.1.

Group 9. Claims 24-29, drawn to a method of treating a condition by administering the antagonist protein as set forth in claim 23 (ii), classified in Class 424, subclass 85.1.

Group 10. Claims 24-29, drawn to a method of treating a condition by administering the antagonist protein as set forth in claim 23 (iii), classified in Class 424, subclass 85.1.

Group 11. Claims 38-64, 66-73, drawn to a gene fusion comprising an affinity handle and a polynucleotide of nucleotide sequence set forth in SEQ ID NO:4, classified in Class 530, subclass 402.

Group 12. Claims 38-64, 66-73, drawn to a gene fusion comprising an affinity handle and a polynucleotide of nucleotide sequence set forth in SEQ ID NO:1, classified in Class 530, subclass 402.

Group 13. Claims 38-64, 66-73, drawn to a gene fusion comprising an affinity handle and a polynucleotide of nucleotide sequence set forth in claim 38 (iii), classified in Class 530, subclass 402.

Group 14. Claims 38-64, 66-73, drawn to a gene fusion comprising an affinity handle and a polynucleotide of nucleotide sequence set forth in claim 38 (iv), classified in Class 530, subclass 402.

Group 15. Claims 38-64, 66-73, drawn to a gene fusion comprising an affinity handle and a polynucleotide of nucleotide sequence set forth in claim 38 (v), classified in Class 530, subclass 402.

Group 16. Claims 74-77, drawn to a method of purifying a fusion polypeptide, classified in Class 530, subclass 417.

Group 17. Claim 79, drawn to a compound having a three dimensional structure and capable of high-affinity binding to CXCR1 and CXCR2 receptors, Class and subclass undeterminable.

Should any one of the Groups from 1-16 be elected, Applicant is required to select one polypeptide (one amino acid sequence) as set forth in claim 23. Once one polypeptide sequence is selected, all other sequences will be withdrawn from consideration.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-7, 11-15, 17, are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The polynucleotides of inventions 1-4 can be used to make hybridization probes or can be used in gene therapy as well as in the production of the specific proteins of interest. The proteins of inventions 5-7 can be used as probes, or used therapeutically or diagnostically, e.g. in screening. The gene fusions with the affinity handles of inventions 11-15 can be used in diagnostics. Each of the polynucleotides of inventions I-4 can be used to produce specific polypeptides.

Inventions I-4 and 5-7 are related as processes of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case each of the proteins can be prepared by materially different processes, such as by chemical synthesis.

Inventions 5-7 and 8-10 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions 5-7 can also be used as an antigens in the production of specific antibodies.

Inventions 1-4 and 11-15 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions I-4 can also be used in gene therapy.

Inventions 1-4, 8-10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 11-15 and 8-10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Invention 17 and 8-10, 16, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 8-10, 16 are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

2. This application contains claims directed to the following patentably distinct species of the claimed invention as recited in claim 29:

There are disparate pathologies

(a) ischemia-reperfusion injury;

(b) endotoxemia-induced acute respiratory distress syndrome;

© immune complex-type glomerulonephritis;

(d) bacterial pneumonia; and

(e) mastitis.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 25-28 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be

allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
August 16, 2004